



5.D. A section for Professional Labeling should be added to the monograph.

Antigingivitis and antigingivitis/antiplaque products have been a valuable tool for dentists to help patients address their oral hygiene needs. Such products are often used as site-specific oral irrigates following surgical or hygienic procedures to help cleanse microbes and debris from the gum area and oral cavity. The antigingivitis/antiplaque products may be prescribed for other uses by the dentist, as he or she sees the need. As this rulemaking progresses, it is likely that companies will file clinical data supporting the professional uses of these products. We request the Agency, at the appropriate time, include a professional labeling section in the monograph to incorporate these uses by dental professionals.

Professional Labeling

The term “professional labeling” first appeared in the OTC Drug Review in the final antacid monograph. FDA subsequently defined professional labeling in the preamble of the final monograph on OTC bronchodilator drugs⁷⁶, as follows:

The Agency defines professional labeling as information that is provided to health care professionals only and not to the general public. There are often situations in which the use of OTC drug products requires the supervision of a physician [or dentist] In these situations, professional labeling provides information to the physician concerning such things as dosage or other indications for the OTC drug products. This information is generally not found in the labeling or package inserts made available to consumers or in publications such as the Physician's Desk Reference (PDR) for Non-prescription Drugs. Information in professional labeling is made available to health

⁷⁶ Federal Register. 51:191 (October 2, 1986), p. 35337

*professionals through literature and samples provided by
representatives of the drug companies, through advertisements in
professional books such as the PDR discussing prescription drugs.*